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09/676,032 09/29/00 AGYIN

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EXAMINER

HM22/1106

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ART UNIT

PAPER NUMBER

1614

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/676,032

Applicant(s)  
AGYIN et al.

Examiner  
Cybille Delacroix-Muirheid

Art Unit  
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on July 18, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3-5 20) ☐ Other:

### **DETAILED ACTION**

Claims 1-25 are presented for prosecution on the merits.

#### ***Information Disclosure Statement***

Applicant's Information Disclosure Statements received Nov. 20, 2000, June 27, 2001 and July 18, 2001 have been considered. Please refer to Applicant's copies of the 1449s submitted herewith.

The Information Disclosure Statement received Oct. 30, 2000 has been considered in part, i.e. US patents only. The remaining references are not in the parent application 08/857,811. The references must be submitted so that they may be considered and made of record.

#### ***Specification***

1. The disclosure is objected to because of the following informalities: there are two "Table 4's" in the specification one at page 18 , the other at page 32.

Appropriate correction is required.

#### ***Claim Objections***

2. Claims 6, 8, 11, 17 are objected to because of the following informalities: in claims 8 and 11, line 1, "which" should be deleted and --wherein the compound-- should be inserted before the "is." In claim 17, line 1, "enhanced" should be deleted and --effective-- should be added. Claim 6 is objected to because it is dependent upon itself. Appropriate correction is required.

3. Applicant is advised that should claim 7 be found allowable, claim 19 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 7 and 19 are identical in scope.

#### *Priority*

Applicant's claim for priority to parent application 0/857,811 is noted. However, A claim can only have one effective filing date. Please see Studiengesellschaft Kahle m.b.H. v. Shell Oil Co., 42 USPQ2d 1674, 1677 (Fed. Cir. 1997). In the instant application the haloalkyl, cycloalkyl, alkoxy and alkenyl groups for substituent R1 have support back to 08/857,811 which was filed May 16, 1997; however, the remaining chemical moieties for R1 do not have support in the earlier filed parent application. Since the claim as whole can only have one effective filing date, the claims of the instant application will be treated as having an effective filing date of September 29, 2000. An intervening art applied in a rejection may be overcome by cancelling the relevant claim limitations or where appropriate, by submitting an affidavit or declaration under 37 CFR 1.131 to antedate the intervening art.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Agarwal et al. (abstract only) or Ram et al. (abstract only).

Agarwal et al. disclose benzimidazole compounds that read on Applicant's claimed generic compound of claim 1. Please refer to the abstracts submitted herewith, with specific reference to RN 153213-42-4; 153213-39-9; 153213-40-2; 153213-41-3.

Ram et al teach benzimidazole compounds that read on Applicant's claimed generic compound of claim 1. Please refer to the abstract submitted herewith, with specific reference to RN's 135696-80-9; 135720-68-2; 135891-47-3.

6. Claims 7, 19, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Naim et al. (abstract only).

Naim et al. describe benzimidazole compounds embraced by Applicant's claimed formula wherein said compounds are potentially useful as anthelmintics. An oral composition containing 25-250 mg/kg of these compounds showed anthelmintic activity. Please see the abstract submitted herewith.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1-4, 7-11, 13, 17-20, 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Camden 6,077,862.

Camden discloses benzimidazole compounds represented by the formula at col.2 , lines 35-46, wherein R is CO<sub>2</sub>R', with R' comprising alkoxy, haloalkyl, alkenyl and cycloalkyl. The compounds and their pharmaceutical addition salts have anti-viral and anti-cancer activity and may be formulated into pharmaceutical compositions (oral or injection) or unit dosage forms for therapeutic use. The dose may range from 15mg to 1500mg/kg of body weight. Moreover, Camden discloses that the compositions may be combined with chemotherapeutic agents or potentiators so as to increase the efficacy of the composition. Please see col. 2, line 28 to col. 4, line 65; col. 6, line 14 to col. 8, line 64; col. 9, lines 10-11 and line 30 to col. 10, line 20; Example 1.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2-16 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agarwal et al. or Ram et al.

Agarwal et al. or Ram et al. disclose numerous benzimidazole compounds which read on the claimed generic compound, wherein the prior art compounds have various pharmaceutical activities, i.e. antineoplastic activity (Ram), anti-helminthic activity (Agarwal). Please refer to the abstracts submitted herewith.

Said references do not specifically disclose pharmaceutical compositions or unit dosage forms comprising the disclosed compounds; however, it would have been obvious to one of ordinary skill in the art to modify the compounds of the prior art into a pharmaceutical composition or a unit dosage form because one of ordinary skill in the art would reasonably expect the compositions to be useful in treating cancer (Ram) or parasitic infections.

With respect to the specific pharmaceutical carriers and pharmaceutical forms or prodrugs, these are all art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to modify them in the teachings of the prior art.

Concerning the claimed dosages, modification of dosage amounts is obvious and well within the capability of the skilled artisan.

Finally, concerning the pharmaceutical kit claim containing the instructions for use in treating cancer or viral infections (claim 25), modification of a composition into kit form is obvious and well within the capability of the skilled artisan. Moreover, the intended use of the composition embodied by the instructions is given no weight and fails to distinguish the claimed composition from the prior art.

11. *→ cancelled* Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ram et al.

Ram et al. disclose methods of studying the antineoplastic activity of benzimidazole compounds embraced by Applicant's claims. Please see abstract. Results show that the benzimidazole compounds inhibit the growth of leukemia cells. See abstract.

Ram et al. do not specifically disclose pharmaceutical compositions of the benzimidazole compounds; however, it would have been obvious to one of ordinary skill in the art to modify the methods of Ram et al. to form pharmaceutical compositions of the benzimidazole compounds because in view of the desirable tumor growth inhibiting activities disclosed by Ram et al., one of ordinary skill in the art would reasonably expect the compositions to be useful in inhibiting the growth of leukemia cells in animal patients.



Moreover, Ram et al. do not teach combining the benzimidazole compounds with a chemotherapeutic agent and/or potentiators; however, it would have been obvious to one of ordinary skill in the art to combine known chemotherapeutic agents and potentiators with the anti-neoplastic compounds taught by Ram et al. because one of ordinary skill in the art would reasonably expect the additive effect of these compounds to more effectively treat the animal suffering from cancer, i.e. leukemia.

12. Claims 8-16 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naim et al., supra.

Naim et al. as applied above.

Naim et al. do not specifically disclose specific pharmaceutical carriers and pharmaceutical forms or prodrugs; however, these are all art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to modify them in the teachings of the prior art with the reasonable expectation that the resulting compositions would retain their pharmaceutical activity.

Finally, concerning the pharmaceutical kit claim containing the instructions for use in treating cancer or viral infections (claim 25), modification of a composition into kit form is obvious and well within the capability of the skilled artisan. Moreover, the intended use of the composition embodied by the instructions is given no weight and fails to distinguish the claimed composition from the prior art.

13. Claims 5, 12, 14-15, 21, 23, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camden, supra.

Camden as applied above.

However, Camden does not specifically disclose liposomal or polymer carriers; however, these are art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to modify them in the teachings of the prior art. Furthermore, concerning the pharmaceutical kit claim containing the instructions for use in treating cancer or viral infections (claim 25), modification of the compositions of Camden into kit form containing treatment instructions is obvious and well within the capability of the skilled artisan.

### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 10, 21-25, 30, 34-36 of copending Application No. 08/857,811. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and USAN '811 claim pharmaceutical compositions comprising the claimed benzimidazole compounds, wherein the

difference between the instant application and USAN '811 is that USAN '811 claims a more limited genus of compounds, with R (which corresponds to R1 in the instant application) comprising alkoxy or haloalkyl.

However, the scope of the claims of the instant application and those of '811 overlap because at least one of the R substituents is identical with the R1 substituents in the instant application and further because the more limited genus claimed in '811 is encompassed by the broader genus claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Conclusion*

Claims 1-25 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

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Applicant: AGYIN et al.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM



Nov. 3, 2001



Cybille Delacroix-Muirheid  
Patent Examiner Group 1600